20 May 2021
EMA/CHMP/153636/2021
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Ozawade

pitolisant

On 20 May 2021, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Ozawade, intended for the treatment of excessive daytime sleepiness in obstructive sleep apnoea.

The applicant for this medicinal product is BIOPROJET PHARMA.

Ozawade will be available as 4.5 mg and 18 mg film-coated tablets. The active substance of Ozawade is pitolisant, a H3-receptor antagonist/inverse agonist (ATC code: N07XX11) which enhances the activity of brain histaminergic neurons.

The benefits of Ozawade are its ability to improve wakefulness in patients with obstructive sleep apnoea. The most common side effects are headache and insomnia.

The full indication is:

> Ozawade is indicated to improve wakefulness and reduce excessive daytime sleepiness (EDS) in adult patients with obstructive sleep apnoea (OSA) whose EDS has not been satisfactorily treated by, or who have not tolerated, OSA primary therapy, such as continuous positive airway pressure (CPAP).

Ozawade should be prescribed by physicians experienced in the treatment of OSA.

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion

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